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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,206	02/09/2001	Michael Fritz	RDID0028US	5556

48801 7590 03/12/2007

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	03/12/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/780,206
Filing Date: February 09, 2001
Appellant(s): FRITZ ET AL.

Patrick G. Gattari
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/29/06 appealing from the Office action mailed 10/24/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,593,838	ZANZUCCHI	01-1997
6,093,370	YASUDA	07-2000
US2003/0027203A1	FIELDS	02-2003
6,126,804	ANDERSEN	10-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 36-41, 69-73, 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (US 5,593,838).

Zanzucchi et al. teach an apparatus of 36, 70, 77-78 for detecting nucleic acids in a sample (see col. 2, line 21-43, col. 4, line 15-62, Fig. 2) comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 4, line 15-40, line 51-54, col. 5, line 50-60, Fig. 2-3, col. 6, line 51-58, Fig. 1B. wherein, Fig. 2-3 indicates a binding space (36) and Fig. 1B. indicates the collection of impurities);

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 4, line 40-42, Fig. 1B and Fig. 2, indicating a part of a binding space includes an amplification space (40), said binding space and amplification space are connected through capillary channel (38));

(c) a detection space for detecting the nucleic acids (see col. 4, line 42-51, Fig. 2 indicating detection space (44)).

With regard to claims 37, 73, Zanzucchi et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 15-33, col. 10, line 66, col. 12, line 42-60, col. 2, line 40-60);

With regard to claims 39, 41, 76, Zanzucchi et al. teach that the amplification space comprises capillary space made up of glass (see col. 6, line 15-25, the microlaboratory disc comprising amplification space is made up of glass, which acts as semiconductor, also see Fig. 5b, and col. 8, line 35-52, indicating complete capillary space is covered or made up of glass);

With regard to claim 40, 79, Zanzucchi et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal layer (see col. 6, line 59-67, metal layer indicates a heatable element);

With regard to claims 38, 69, Zanzucchi et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see col. 4, line 35-54, indicating that the binding space, amplification space and detection space are inter connected to facilitate the flow of the fluids);

With regard to claims 71, Zanzucchi et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 9, line 15-33).

With regard to claim 72, Zanzucchi et al. teach a binding space for binding nucleic acids (see col. 9, line 15-33); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 10, line 6-42, col. 12, 42-60); and a sample transport mechanism which transports the sample and reagents through the space (see col. 12, line 42-60, indicating plurality of modules on a microlaboratory space for sample transport) Thus the disclosure of Zanzucchi et al. meets the limitations in the instant claims.

B. Claims 36-41, 68-73, 76-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Yasuda et al et al. (US 6,093,370).

Yasuda et al. teach an apparatus of 36, 70, 77-78, for detecting nucleic acids in a sample comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 22, col. 9, line 5-27, Fig. 7 indicates DNA binding space (731 and 733), also Fig. 21-23 indicate binding space (431));

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 9, line 27-36, col. 22, line 28-36, Fig. 7, indicates for amplification space (733), also see col. 17, line 11-27, Fig. 21-23, indicate amplification space (431);

(c) a detection space for detecting the nucleic acids (col. 9, line36-40, col. 22, line 37-43, Fig.7 indicates detection space and analysis (732), also see col. 17, line 35-53, Fig. 23-24 indicates detection space (401, 444)).

With regard to claims 37, 73, Yasuda et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 5-67, col. 10, line 23-53);

With regard to claims 39, 41, 76, Yasuda et al. teach that the amplification space comprises capillary space made up of glass (see col. 16, line 24-48, Fig. 20-21);

With regard to claim 40, 79, Yasuda et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal (chromium) layer (see col. 16, line 33-36, Fig. 20-21);

With regard to claim 68, Yasuda et al. teach an apparatus comprising capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (see col. 16, 29-48, Fig. 20, 21, indicating a capillary tube coated with a metal layer, col. 23, line 11-34);

With regard to claims 38, 69, Yasuda et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see col. 9, line 5-40, indicating that the binding space, amplification space and detection space are inter connected to facilitate the flow of the fluids);

With regard to claims 71, Yasuda et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 4, line 54-60, col. 9, line 5-40).

With regard to claim 72, Yasuda et al. teach that apparatus comprises a space for binding nucleic acids (se col. 4, line 54-60, col. 9, line 5-40); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 9, line 5-67, col. 10, line 23-53); and a sample transport mechanism which transports the sample and reagents through the space (see col. 9, line 5-40, indicating 711, 712, 713 for sample transport inlets for transporting sample and reagent solutions). Thus the disclosure of Yasuda meets the limitations in the instant claims.

C. Claims 68 is rejected under 35 U.S.C. 102(e) as being anticipated by Anderson (USPN. 6,126,804).

Andersen teaches an apparatus of claim 68, for amplifying nucleic acids comprising a capillary reaction vessel (see col. 7, line 30-67, col. 8, line 1-4) surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (electrically conductive coating made up of a metal, see col. 8, line 13-22). Accordingly the instant claim is anticipated by Andersen.

D. Claims 36-38, 69-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Fields (US 2003/0027203).

Fields teaches an apparatus of 36, 70, for detecting nucleic acids in a sample (see page 2, paragraph 0022) comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5);

(b) an amplification space for amplifying the nucleic acids (see fig. 6, paragraph 0063) wherein a part of amplification space is identical to a part of an amplification space (see Fig. 6, wherein the vial 420 is connected to amplification space by capillary tubes);

(c) a detection space for detecting the nucleic acids (see paragraphs 0063, indicates the amplified products are moved into device 425, for detection of amplified nucleic acid products).

With regard to claims 37, 73, Fields teaches that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see page 3, paragraphs 0031-0034);

With regard to claims 38, 69, Fields teaches that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see Fig. 1-3 and Fig. 6, wherein the detection space comprises a part of amplification space and a part of the binding space connected by a 3-way and four-way connecting tubes facilitating transport of sample and reagents, page 3, paragraph 0049-0054);

With regard to claims 71, Fields teaches that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see page 4, paragraph 0061).

With regard to claim 72, Fields teaches that the apparatus comprises a space for binding nucleic acids (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5); reagents for amplifying and detecting nucleic acids bound to the surface (see (see page 3, paragraphs 0031-0034); and a sample transport mechanism which transports the sample and reagent (see page 3, paragraph 0049-0054). Thus the disclosure of Fields meets the limitations in the instant claims.

Response to arguments:

Introduction

The anticipation rejections of the instant claims depend on four independent references; they are Zanzucchi et al (US 5,593,838), Yasuda et al (US 6,093,3701), Fields (US patent publication No. 2003/0027203) and Andersen et al. (US 6,126, 804). The instant claims are drawn to an apparatus and the claims while reciting the components of the apparatus, also recite the intended use of the parts of the apparatus. The anticipation is mainly based on the 'at least part of the space". All the references do teach at least part of the space as capillary channels connecting the spaces or wells.

Appellants' assertions on page 4-6 with regard to the reference Zanzucchi et al. are fully considered. Appellants assert that Zanzucchi et al. does not teach a binding space for purifying nucleic acids by immobilizing nucleic acids and separating impurities, and at least a part of binding space instead teaches a Luekosorb media to filter blood cells from the sample in the first well and a channel connecting the first well to the second well. Appellants also assert that Zanzucchi et al. does not teach at least a part of an amplification space is identical to at least a part of a binding space. The assertions are not persuasive because on col. 4, lines 15-40, and col. 8 line 7-11, Zanzucchi et al. teach a filtering and lysing the blood on the filter and isolating

DNA, which clearly indicate that the nucleated white blood cells are trapped on the filter while lysing the red blood cells and the impurities (lysed red blood cells) are separated and the isolated DNA is moved in to a second well by capillary channel connected between the first and second well. The instant claims recite 'at least a part of the amplification space' is identical to a part of the binding space, which does not necessarily mean that the at least part of the space participates in binding DNA and amplification of DNA. Moreover the recitation of 'at least a part of ' could be a connecting capillary channel and the structure is identical to the at least a part of the binding space. Appellants ' assertion that the interpretation cannot be true because one space comprises at least a part of the other which is not persuasive because if the connecting channel is not present the spaces can be treated as separate wells and since the wells are connected to each other it is treated as one space comprising at least a part of the other and it is not necessarily overlapping spaces as asserted by the Appellants and the claim 36 does not recite that the at least a part of is an overlapping space between two spaces. Examiner also notes that the instant claims are drawn to an apparatus and the limitations on immobilizing DNA separating impurities, amplifying and detecting nucleic acid are intended use of the apparatus, as stated in MPEP 2114 A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

On page 6-7 of the appeal brief Appellants assert that Zanzucchi et al. teach an etching process for making the channel and wells and the interpretation of capillary reaction vessel surrounded by a heatable layer is not accurate. Appellants assertions are fully considered,

however, as discussed in the rejection Zanzucchi et al. does teach a heatable metal layer (glass layer) surrounding the wells and channels and the process of making the layer is irrelevant to the present context and the instant claims are in open comprising format thus the instant claims do not exclude additional elements as etching metal layer on the vessel. Further the claim 79 recites that the metal layer is exterior of the vessel, which clearly is anticipated by Zannuachi et al. because the metal layer is exterior to the vessel (well) taught by Zannuchi et al.

On page 8-10 of the appeal brief Appellants assert that Yasuda et al. does not teach at least a part of amplification space is identical to at least a part of the binding space and assert that the temperature of the three chambers taught by Yasuda et al. are individually controlled. Appellants also assert Yasuda et al. does not teach at least apart of detection space is identical to at least a part of the amplification space. As discussed above the broader scope of the instant claims, do not exclude the teachings of Yasuda. As discussed in the rejection does teach at least a part of amplification space is identical to at least a part of the binding space. The assertion on temperature control of the three chambers is not relevant to the instant claims. Appellants also assert that Yasuda et al. teaches a polynucleotide separation apparatus and does not teach amplification in the at least part of the binding space. Examiner notes that the instant claims do not require that the binding and amplification take place in the same space. On page 10-11 of the appeal brief Appellants assert that Yasuda et al. does not teach a heatable metal layer surrounding the reaction vessel. With regard to the Appellants' assertions that Yasuda et al. does not teach heatable metal layer surrounding the vessel, the heatable metal layer taught by Yasuda is a glass capillary wherein the inner surface is coated with a stable oxide, thus the glass

represents heatable metal layer which surrounds the reaction space wherein the inner surface is coated with an oxide.

On page 12-13 of the appeal brief Appellants assert that Fields does not teach at least a part of the amplification space is same as the at least a part of the binding space and at least a part of the detection space is same as the at least a part of the amplification space and the Examiner has misinterpreted the capillary connecting tubes and three –way and four-way valves as 'at least a part is same', is in correct. With regard to the assertions, Examiner notes that as discussed in the rejection the three-way connecting valves unite all the three spaces and thus the limitation that 'at least part of the space' does read on the instant claims. Further the instant claims do not require that at least the part of the space that is common or identical to the three spaces do the required function. With regard to the claim 72, Appellants assert that Fields does not teach a heatable metal layer however the discloser of Fields capillary connection tubes are temperature controlled blocks in the form of microplate or DNA chip (see at least page 6, paragraph 0072, and 0063).

On page 14 of the appeal brief Appellants assert that Andersen does not teach a single heatable metal layer surrounding a reaction vessel and the Examiner has misinterpreted the coating of an electrically conductive material and capillary electrophoretic column as the heatable layer as the metal layer is not applied to the cover plate . The instant claim recites metal layer surrounding the reaction vessel which broadly reads on the teaching of Andersen because Andersen teach that the capillary vessel is made up of a metal (glass) that is heatable layer that does teach a metal layer surrounding the capillary space and said capillary and cover plate are made up of the heatable metal layer, that is, made up of glass.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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